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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,088	06/19/2001	Peter Jan Leonard Mario Quaedflieg	24615-20145	9816

25225 7590 01/06/2005
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EXAMINER

SHIAO, REI TSANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,088

Applicant(s)

QUAEDFLIEG ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 11/12, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 12-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/12/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application:
EUROPEAN PATENT OFFICE (EPO) 98204371.3 with a filing date 12/22/1998.
2. The SEQ ID NO:1 of the sequence list filed on 01/09, 2002, is not identified. Applicants are requested to file a clear version of sequence list to the Office.
3. Claims 1-19 are pending in the application.

Responses to Election/Restrictions

4. Applicant's election with traverse of Group I claim 1, in part, and 6-11 in the reply filed on November 12, 2004, is acknowledged. The traversal is on the grounds that instant invention of Group I-IV share a special technical features. This is not found persuasive because Inventions of Groups I-II and III-IV are independent and distinct products and processes of making different products because starting materials (i.e., formula (1), or (2)), solvent, catalyst, and reaction conditions of each group differ in elements, bonding arrangement and chemical property to such an extend that a reference anticipating processes of making of any one group would not render another group obvious. However, since the peptide deformylase of claims 4-5 are commensurate with the scope of Group I, therefore, claims 4-5 of Group II are rejoined herein with Group I, and claims 1, 4-11 are prosecuted in the case. Claims 2-3, and 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It is noted that the claims contains subject matter "a compound with enhanced optical purity", which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., see claim 1, line 1.

6. Claims 1, 4-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound, i.e., deformylation of N-formyl-alaninol, does not reasonably provide enablement a compound not having an amino acid moiety, see pages 1-3 of the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention

The claims are drawn to a process for preparing a compound with enhanced optical purity without limitation.

2) State of the prior art

The reference Bogosian's US 5,834,243 does not indicate which compounds of instant compounds may be useful in the claimed invention. Bogosian's '243 is pertaining to deformylation of F-met peptides in bacterial expression systems.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claims are drawn to "a process for preparing a compound with enhanced optical purity without limitation". Applicant's specification does not enable the public to prepare such

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“a process for preparing a compound with enhanced optical purity without limitation” by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claims are drawn to “a process for preparing a compound with enhanced optical purity without limitation”, see claim 1, line 1. Different types of the genus of processes require various experimental procedures and without guidance that is applicable to all possible “a process for preparing a compound with enhanced optical purity without limitation”, there would be little predictability in the scope of claimed processes.

5) Amount of direction and guidance provided by the inventor.

The claims are drawn to “a process for preparing a compound with enhanced optical purity without limitation”, encompasses a vast number of processes. Applicant's limited guidance does not enable the public to prepare such “a process for preparing a compound with enhanced optical purity without limitation” in the specification. There is no enablement for “a process for preparing a compound with enhanced optical purity without limitation”, i.e., a compound not having an amino acid moiety, which are neither enabled nor supported in the specification.

6) Existence of working examples.

The claims are drawn to “a process for preparing a compound with enhanced optical purity without limitation”, encompasses a vast number of processes. Applicant's limited working examples do not enable the public to prepare such a numerous amount of “a process for preparing a compound with

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enhanced optical purity without limitation" in the specification. Applicants claim "a process for preparing a compound with enhanced optical purity without limitation", however, the specification provides only limited examples of the processes.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "a process for preparing a compound with enhanced optical purity without limitation".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous processes in order to obtain "a process for preparing a compound with enhanced optical purity without limitation" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed compounds without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. Incorporation of the limitation of "a process for preparing a compound with enhanced optical purity without limitation", i.e., the deformed compounds of Tables 1-3 on pages 14-16 of the specification.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 4-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of Quaedflieg et al. copending Application No. 09/869,067. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

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Applicants claim a process of preparing a compound with enhanced optical purity which comprises contacting an enantiomers compound of formula (1), wherein the variables R^1 and R^2 of the compound of formula (1) independently represent hydrogen, alkyl or aryl, the variable Y represents CH_2OH or $C\equiv N$, in the presence of an enzyme having peptide deformylase activity. This process is found on the pages 1-33 of the specification.

Quaedflieg et al. claim a process for preparing a α -aminonitrile compound with enhanced optical purity which comprises contacting an enantiomers compound α -aminonitrile in the N-formyl form (i.e., N-formyl-phenylalanine aminonitrile) in the presence of an acylase (i.e., peptide deformylase).

The difference between the instant claims and Quaedflieg et al. is that the instant starting materials having a CH_2OH or $C\equiv N$ (i.e., aminonitrile) moiety, while Quaedflieg et al. have an aminonitrile moiety.

One having ordinary skill in the art would find the claims 1, 4-11 prima facie because one would be motivated to employ the processes of Quaedflieg et al. to obtain instant processes, wherein a compound (i.e., α -aminonitrile) with enhanced optical purity is prepared using a starting material of formula (1), wherein the variables R^1 and R^2 of the compound of formula (1) independently represent hydrogen, alkyl or aryl, the variable Y represents $C\equiv N$, in the presence of an enzyme having peptide deformylase activity.

The motivation to make the claimed compounds derives from the expectation that the instant claimed processes would possess similar yields, from the known Quaedflieg et al. processes to that which is claimed in

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the reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1, 4-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of Quaedflieg et al. US 6,617,127. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a process of preparing a compound which comprises contacting an enantiomers compound of formula (1), wherein the variables R^1 and R^2 of the compound of formula (1) independently represent hydrogen, alkyl or aryl, the variable Y represents $(CH_2)_nCOOH$, $(CH_2)_n-COOR$, $(CH_2)_n-CONRR'$, CH_2OH or $C\equiv N$, in the presence of an enzyme having peptide deformylase activity. This process is found on the pages 1-33 of the specification.

Quaedflieg et al. claim a process for preparing a α -L-aspartyl-phenylalanine methyl ester compound by enzymatic deformylation of an N-formyl- α -L-aspartyl-phenylalanine or its methyl ester in the presence of an enzyme having peptide deformylase activity.

The difference between the instant claims and Quaedflieg et al. is that the instant starting materials of formula (1) have a $(CH_2)_nCOOH$, $(CH_2)_n-COOR$, $(CH_2)_n-CONRR'$, CH_2OH or $C\equiv N$, moiety, while Quaedflieg et al. have a carboxylic moiety (i.e., $(CH_2)_nCOOH$, or $(CH_2)_n-COOR$).

One having ordinary skill in the art would find the claims 1, 4-11 prima facie

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because one would be motivated to employ the processes of Quaedflieg et al. to obtain instant processes, wherein a compound is prepared using a starting material of formula (1), wherein the variables R^1 and R^2 of the compound of formula (1) independently represent hydrogen, alkyl or aryl, the variable Y represents $(CH_2)_nCOOH$, $(CH_2)_n-COOR$, $(CH_2)_n-CONRR'$, CH_2OH or $C\equiv N$, in the presence of an enzyme having peptide deformylase activity.

The motivation to make the claimed compounds derives from the expectation that the instant claimed processes would possess similar yields, from the known Quaedflieg et al. processes to that which is claimed in the reference.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707.

The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

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PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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1/4/05.



Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

January 04, 2005